January 2022

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Phoxilium 1.2mmol/l phosphate Solutions for haemodialysis/haemofiltration: supply of non-UK labelled batches during the Covid-19 Pandemic

Dear Healthcare Professional,

Summary:

To ensure continuity in supply, Baxter Healthcare Limited has obtained approval from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply multi-lingual packs intended for the French market.

Product Name and MA Number	Active ingredients	UK Product Code	Replacement Product Code	Labelling Language	Batch Numbers
Phoxilium 1.2mmol/l phosphate PL00116/0708	Calcium chloride dihydrate, magnesium chloride hexahydrate, sodium chloride, potassium chloride, sodium hydrogen carbonate, disodium phosphate	113637	113638	French, German and Dutch	21J2810 21J2811 21J2812

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to patients.

Please note the following:

- The replacement products are identical to product you will have already been using. The bags are fully compatible with the continuous renal replacement therapy (CRRT) systems on which you currently use Phoxilium.

- The only difference is the languages of the product information. A comparison of the labelling is provided as an annex to this letter. The labels have key similarities to those of the UK approved product:
    - The product name is the same “Phoxilium”.
    - The ink colour used to identify the product on the primary and carton labels is the same green as UK Phoxilium
    - The labelling format for presentation of ingredients amounts, chemical formula etc.

Baxter Healthcare Ltd
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Registered Office: Caxton Way / Thetford / Norfolk / IP24 3SE Registered in England No. 461365

- Please ensure the UK Summary of Product Characteristics and package leaflet for Phoxilium are followed. Both documents can be found on the Electronic Medicines Compendium at the following link: www.medicines.org.uk/emc/product/2140

  Alternatively, copies of the Summary of Product Characteristics and package leaflet can be obtained from Baxter Medical Information, details below. Copies of the UK labelling can also be provided.

Do you need to do anything different when it comes to placing an order?

No, you order as you always would, using the normal product code. The substitution will be done behind-the-scenes by Baxter Customer Services, once we receive your order. You just need to make sure you communicate amongst your staff, so that they aware that the product code they receive on the ICU, may be different to what they normally expect.

You will be charged the same as for your normal product code.

Call for reporting

Healthcare professionals are asked to report suspected adverse reactions to the Yellow Card Scheme electronically. Report via the website https://yellowcard.mhra.gov.uk/, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789 for free.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Adverse Events relating to Baxter products can also be reported direct to Baxter Pharmacovigilance on 01635 206360, or by email to vigilanceuk@baxter.com.

Any drug product quality complaints (including suspected defective medicines) relating to Baxter products can be reported directly to the Baxter Country Quality Assurance Team on 01604 704603, or by email to UK_SHS_QA_Complaints@baxter.com.

Company contact point
If you have any questions about this letter or require more information about Phoxilium, please contact Baxter Medical Information on 01635 206345 or email medinfo_uki@baxter.com.

Yours faithfully

Andrew Warburton
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Baxter UK and Ireland

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Comparison Table of product labelling - UK vs replacement product

	UK Phoxilium Product code 113637	Phoxilium FR/NL/DE language Product code 113638
Bag Label - Front		

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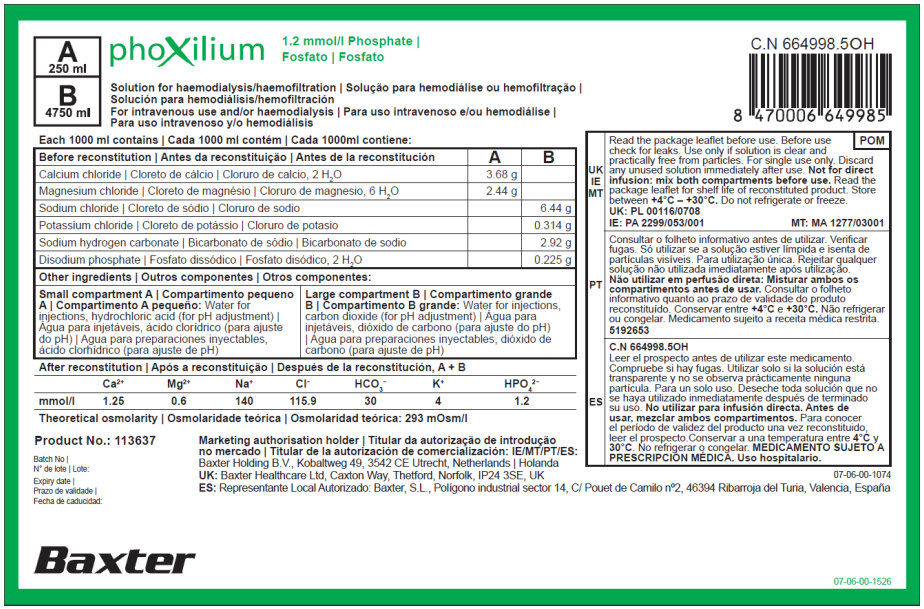
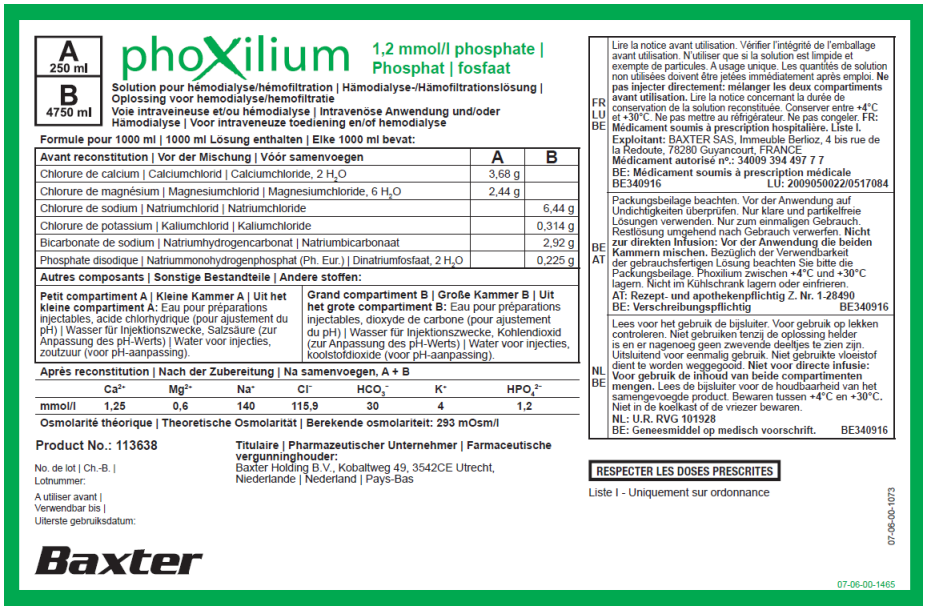
	UK Phoxilium Product code 113637	Phoxilium FR/NL/DE language Product code 113638
Bag Label - Reverse	Open seal ↓ Abra o selo ↓ Abrir sello ↓	Ouvrir la soudure pelable ↓ Der Trennnaht öffnen ↓ Open de lasnaad ↓
Code Specific Carton Label		

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Rev. 2014-04

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